

## REMARKS

The original title has been canceled and new title submitted which more accurately reflects the subject matter of the instant claims.

The paragraph spanning lines 9-18 on page 6 of the specification has been replaced with a substitute paragraph. In the new paragraph, the duplicate sentence spanning lines 14-16, has been deleted. In addition, in response to the Examiner's contention that the paragraph contains terminology abhorrent to normal use, Applicants have modified the language defining the words 'ã' and 'ai' so as to clarify the intended meaning of these words.

The paragraph spanning lines 15-23 on page 10 of the specification has been replaced with a substitute paragraph. In the new paragraph, several nonsensical words have been deleted.

The paragraphs spanning lines 7-23 on page 12, through lines 1-5 on page 14 have been replaced with a substitute paragraph. In the new paragraph, a period has been inserted after the word 'antigen' (page 14; line 1). Further, the US Patent Serial No. (page 13, line 23) has been changed to reflect the issuance of that application as a patent. Finally, the spelling of the word 'possess' has been corrected on page 14, line 3.

The paragraph spanning lines 1-3 on page 3 of the specification has been replaced with a substitute paragraph. The new paragraph correctly identifies the symbols as squares and circles used in Figure 1.

The paragraph spanning lines 11-17 on page 38 of the specification has been replaced with a substitute paragraph. In the new paragraph, in line 16 the word 'immitis' has been spelled using a lower case 'i'.

The paragraph spanning page 39, lines 18-22, through page 40, lines 1-14, has been replaced with a substitute paragraph. The new paragraph, in referring to Figure 6, refers to 9 groups instead of 10. Reference to a heat-inactivated heartworm-infected sera pool has been deleted.

The paragraph spanning page 41, lines 13-22, through page 42, lines 1-7, of the specification has been replaced with a substitute paragraph. In the new paragraph, in line 16 the spelling of the word 'clarified' has been corrected.

The paragraph spanning lines 1-10 on page 45 of the specification has been replaced with a substitute paragraph. In the new paragraph, in line 2 the spelling of the word 'anti-canine' has been corrected.

All of the submitted changes merely correct spelling or grammatical errors. In the case of paragraphs which refer to figures, the changes merely correct the number of samples represented to in the figure or the symbols used in the referenced figure. Accordingly, Applicants submit no new matter has been entered into the Application.

#### Rejections Under 35 U.S.C. §103(a)—obviousness

The Examiner has rejected Claims 106-115 as being unpatentable over Kinet *et al.* (U.S. Patent No. 5,770,396; hereafter referred to as Kinet) in view of Zuk *et al.* (U.S. Patent No. 4,208,479; hereafter referred to as Zuk). The Examiner states Kinet teaches the isolated human Fc epsilon receptor alpha chain protein comprising amino acid sequences of the instant invention. The Examiner acknowledges that Kinet does not teach labeling the receptor with detectable markers. To remedy this lack of teaching, the Examiner cites Zuk which, according to the Examiner, teaches general principles for labeling receptors with a variety of markers. The Examiner therefore concludes it would have been obvious to anyone skilled in the art to label the receptor of Kinet using the procedures taught by Zuk. Applicants respectfully disagree and contend that not only is there no motivation to make the suggested combination, but that even if the references were properly combinable, Zuk is not enabling for the labeling of immunoglobulin receptors.

The instant claims are drawn to human IgE receptor alpha chain protein which has been conjugated to a detectable marker through carbohydrate groups on the receptor. Applicants acknowledge the isolated human IgE receptor alpha chain protein was disclosed by Kinet. However, as acknowledged by the Examiner, Kinet did not teach or suggest labeling the receptor. The Examiner has cited Zuk as providing the teaching and motivation necessary to label the receptor of Kinet. However, Applicants note that while Zuk does provide the general idea of labeling receptors, the actual substantive teaching of Zuk relates exclusively to labeling antibodies, and in particular, immunoglobulin gamma (IgG); see, for instance, Examples 1 and 2. Applicants contend Zuk fails to provide substantive guidance as to how to label receptors other than IgG and, therefore, there is no motivation to apply the substantive teaching of Zuk to the immunoglobulin receptor of Kinet.

Next, while it is true that Zuk discloses a laundry list of molecules and classes of molecules which theoretically could be labeled, Applicants note immunoglobulin receptors, and

in particular IgE receptors, are not present on this list. Furthermore, while immunoglobulin receptors may share characteristics with classes of molecules present in the list of Zuk, Applicants contend that merely providing a laundry list of various classes of molecules into which the IgE receptor may or may not fall does not amount to enabling teaching as to how to label the IgE receptor. It is well appreciated in the art that a particular chemical treatment may have very different effects on two unrelated molecules. Modifications made to a protein which do not effect the activity of that protein may completely inactivate the activity of a different, unrelated protein, making the extrapolation of results unpredictable. Therefore, in the instant case, labeling of immunoglobulin proteins does not enable labeling of immunoglobulin receptor. As noted by the court in *In re Brown*, 141 USPQ 245 (CCPA 1964), references relied upon to support a rejection under 35 USC 103 must provide enabling disclosure; Zuk fails to do so. Instead, Applicants contend the speculative listing of molecules by Zuk amounts to nothing more than an invitation to experiment.

Applicants liken the facts of the instant case to those in *Ex parte Primakoff*, 64 USPQ2d 1848 (BdPatApp & Int 2001). In *Primakoff*, Appellants were claiming a method of contraception in a non-Cavia porcells (guinea pig) mammal comprising immunizing the mammal with purified sperm protein PH-20 from the specie of animal being immunized. Appellants own previous work (the Prior Art) had already shown that immunization of guinea pigs with guinea pig PH-20 resulted in 100% effective contraception. The Prior Art also stated the human analogue of PH-20 would be a candidate for a contraceptive immunogen in humans. The Prior Art did not disclose whether such an analogue existed, whether such an analogue would be expected to be structurally similar to the guinea pig protein, or how the human analogue could be purified. The Examiner rejected the claims concluding that, in view of the prior art, Appellants claimed method was obvious. On Appeal, the USPTO Board of Patent Appeals and Interferences (BPAI) reversed the rejection, holding the disclosure of the Prior Art did not make the appealed claims obvious, but rather, presented a classic obvious to try situation. The BPAI concluded that the Prior Art, in stating that similar work could be attempted in humans, merely provided a general disclosure which although might pique a scientists curiosity to experiment further in the area of human immunization, did not provide sufficient teaching as to how to obtain the desired result or that the claimed result would be obtained. According to the Board, "This is the definition of obvious to try."

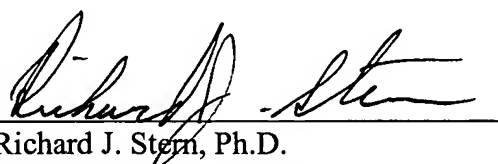
In applying this finding to the instant case, Applicants contend the listing of molecules in Zuk is analogous to the presence in the Prior Art of Primakoff of a sentence stating that the human analogue of PH-20 could be used for immunization. Furthermore, as was found for the Prior Art statement of Primakoff, Applicants contend the mere listing of molecules by Zuk amounts to a general disclosure which fails to provide specific, enabling teaching; in the instant case, the general disclosure of Zuk fails to provide teaching as to whether the IgE receptor could be labeled as taught by Zuk or whether such a labeled molecule would retain activity. Therefore, at best, Zuk provides an invitation to experiment with the labeling of other molecules. As noted by the Board in Primakoff, a general disclosure which fails to provide sufficient teaching but which might pique ones interest to experiment in an area is the definition of 'obvious to try'. Thus, Zuk presents a classic obvious to try situation. In view of this, Applicants contend the combination of Zuk with Kinet fails to make the instant invention obvious.

#### CONCLUSION

In view of the amendments and arguments presented above, Applicants request withdrawal of all objections and rejections and solicit allowance of the pending claims. The Examiner is invited to contact the undersigned should any issues remain.

Respectfully submitted,

Dated: June 9, 2005

By:   
Richard J. Stern, Ph.D.  
Registration No. 50,668  
Heska Corporation  
3760 Rocky Mountain Avenue  
Loveland, Colorado 80538  
Telephone: (970) 493-7272  
Facsimile: (970) 619-3011